

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertension who candidate of open-heart surgery

#### Protocol summary

##### Study aim

Comparison of the effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertension who are candidates for open heart surgery

##### Design

After confirmation of pulmonary artery hypertension disorder, the admitted patients will be randomly assigned to open criculate ligament in two groups: A (Intratracheal milrinone) and B (Intravenous infusion of milrinone). The study is a clinical trial with a sample size of 16 people in parallel groups.

##### Settings and conduct

Patients referred to Ahvaz Golestan Hospital with a history of pulmonary artery hypertension undergoing open heart surgery are included in the study. Measurement of patient echocardiographic and hemodynamic factors such as: systolic blood pressure, diastolic blood pressure, mean arterial pressure (MAP), heart rate (HR), Systolic, diastolic, mean pulmonary artery pressure (MPAP), central venous pressure, systemic vascular resistance (SVR) and PVR, cardiac output, pulmonary indices and (SVR PVRI, SVRI) before and after surgery again in trimester 10, 30 and 60 minutes after surgery will also be measured.

##### Participants/Inclusion and exclusion criteria

patients with pulmonary hypertension enter the study field. If the patient refuses, the presence of COPD and pulmonary hemorrhage are excluded.

##### Intervention groups

1. Milrinone infusion group 0.5mcg/kg/min at the end of CPB pump  
2. Group of administration of 5 cc milrinone intratracheal at the end of CPB pump

##### Main outcome variables

Pulmonary hypertension

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201104049266N1**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

##### Registration date

2020-12-06, 1399/09/16

##### Registrant information

##### Name

sara Joreirahmadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3017

##### Email address

sjaca4913@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-08-22, 1400/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertension who candidate of open-heart surgery

## Public title

effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertention

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

candidated for open heart surgery pulmonary pressure more than 40 mmhg 20 years <age <70 years

### Exclusion criteria:

Patient refusal redo surgery COPD Kindey or Hepatic Failure LVEF<40mmhg Pulmonary bleeding in pulmonary HTN Mean pulmonary artery pressure>25mmhg

## Age

From **20 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **16**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization was performed in a simple and individual manner with emphasis on the patient's case code and using a table of random numbers. In this method, all patients were coded and the code of each disease was randomly assigned to a group.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahwaz Jundishapur University of Medical SCIENCES

##### Street address

cardaic surgery or, Golestan Hospital, Golestan Blvd

##### City

Ahwaz

##### Province

Khouzestan

## Postal code

6135733118

## Approval date

2020-11-02, 1399/08/12

## Ethics committee reference number

IR.AJUMS.REC.1399.654

## Health conditions studied

### 1

#### Description of health condition studied

Pulmonary HTN

#### ICD-10 code

I27.2

#### ICD-10 code description

Other secondary pulmonary hypertension

## Primary outcomes

### 1

#### Description

Mean pulmonary artery pressure

#### Timepoint

During surgery

#### Method of measurement

Using a radial artery catheter and a pulmonary artery catheter and through the left internal jugular vein

### 2

#### Description

Pulmonary capillary wedge pressure

#### Timepoint

During surgery

#### Method of measurement

Using a radial artery catheter and a pulmonary artery catheter and through the left internal jugular vein

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Nebulized milrinone- In patients in this group, 2 mg of milrinone (dissolved in dextrose) is diluted in 3 ml of 9% sodium chloride and inhalation is complete within 15 minutes.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: For patients in this group, 0.25-0.75 µg/kg/min milrinone will be injected intravenously.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Golestan hospital , Ahvaz Jondishapur University of Medical Sciences

**Full name of responsible person**

Sara Joreirahmadi

**Street address**

Khuzestan - Ahvaz - Golestan - Farvardin Blvd

**City**

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**Province**

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**Postal code**

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**Phone**

+98 61 3374 3030

**Email**

sjaca4913@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mahdi Ahmadimoghaddam

**Street address**

Khuzestan - Ahvaz - Golestan - Farvardin Blvd

**City**

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ahmadi-m@ajums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Sara Joreirahmadi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Sara Joreirahmadi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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Ahvaz University of Medical Sciences

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

Anesthesiology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable